



PATENT

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April 27, 2004  
Date

Lawrence Teague

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : John K. Jackson et al.  
Application No. : 10/721,835  
Filed : November 25, 2003  
For : POLYMERIC SYSTEMS FOR DRUG DELIVERY  
AND USES THEREOF

Docket No. : 920041.416C1

Date : April 27, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, applicants wish to make known to the Patent and Trademark Office the references set forth on the attached form PTO-1449. This application is a continuation and relies, under 35 U.S.C. § 120, on the earlier filing date of prior application USAN 09/181,582, filed October 28, 1998. The references listed on the attached forms PTO-1449 were submitted to and/or cited by the Office in this prior application and, therefore, are not required to be provided in the present application. If the Examiner wishes copies will be provided upon request.

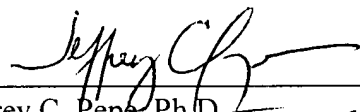
As to any reference supplied, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 C.F.R. § 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicants believe this Information Disclosure Statement has been timely filed, however, the Director is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC

  
\_\_\_\_\_  
Jeffrey C. Pepe, Ph.D.  
Registration No. 46,985

JCP:ljt

Enclosures:

Postcard  
Transmittal Form  
Form PTO-1449 (4 Sheets)

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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

920041.416C1

APPLICATION NO.

10/721,835

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANTS

John K. Jackson et al.

FILING DATE

November 25, 2003

GROUP ART UNIT

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,438,253	03/20/84	Casey et al.	528	86	
	AB	4,452,973	06/05/84	Casey et al.	528	354	
	AC	4,526,938	07/02/85	Churchill et al.	525	415	
	AD	4,716,203	12/29/87	Casey et al.	525	408	
	AE	4,826,945	05/02/89	Cohn et al.	528	76	
	AF	4,882,168	11/21/89	Casey et al.	424	468	
	AG	4,938,763	07/03/90	Dunn et al.	604	891.1	
	AH	4,942,035	07/17/90	Churchill et al.	424	423	
	AI	5,167,649	12/01/92	Zook	604	307	
	AJ	5,278,201	01/11/94	Dunn et al.	523	113	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
*	AK	CA 2,138,474	06/20/96	Canada		
*	AL	EP 241178 A1	10/14/87	EPO		
*	AM	EP 537559 A1	04/21/93	EPO		
*	AN	EP 539741 A1	05/05/93	EPO		
*	AO	EP 737703 A2	10/16/96	EPO		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

*	AP	Bei et al., "Polycaprolactone-Poly (Ethylene Glycol) Block Copolymer III Drug Release Behavior," <i>Chinese J. of Polymer Sci.</i> 13(2): 154-161, 1995.
*	AQ	Cerrai et al., "Block copolymers of L-lactide and poly(ethylene glycol) for biomedical applications," <i>Journal Of Materials Science: Materials In Medicine</i> 5: 308-313, 1994.
*	AR	Cohn and Younes, "Biodegradable PEO/PLA block copolymers," <i>J. of Biomed. Mat. Res.</i> , Vol. 22, 993-1009 (1988)

EXAMINER

DATE CONSIDERED

\* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

\* Not in file

FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 920041.416C1	APPLICATION NO. 10/721,835
<b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)		APPLICANTS John K. Jackson et al.	
		FILING DATE November 25, 2003	GROUP ART UNIT

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA	5,607,686	03/04/97	Totakura et al.	424	426	
	BB	5,626,863	05/06/97	Hubbell et al.	424	426	
	BC	5,667,809	09/16/97	Trevino et al.	424	501	
	BD	5,702,717	12/30/97	Cha et al.	424	425	
	BE	5,944,341	11/30/99	Hunter et al.	514	210	

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	BF					

### OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

*	BG	Gan et al., "Poly( $\epsilon$ -Caprolactone)/Poly(Ethylene Oxide) Diblock Copolymer II. Nonisothermal Crystallization and Melting Behavior," <i>J. of Appl. Polym. Sci.</i> , 1793-1804 (1997)
*	BH	Hu and Liu, "Effect of soft segment on degradation kinetics in polyethylene glycol/poly(L-lactide) block copolymers," <i>Polymer Bulletin</i> 30: 669-676, 1993.
*	BI	Jackson, J.K. et al., "A polymer-based drug delivery system for the antineoplastic agent bis(maltolato)oxovanadium in mice," <i>British Journal of Cancer</i> 75(7): 1014-1020, 1997.
*	BJ	Kimura et al., "Preparation of block copoly(ester-ether) comprising poly(L-lactide) and poly(oxypropylene) and degradation of its fibre <i>in vitro</i> and <i>in vivo</i> ," <i>Polymer</i> 30: 1342-1349, 1989.
*	BK	Lyatskaya and Birshtein, "Triblock Copolymers: the Role of Interfacial Tension Coefficients at Two Interfaces," <i>Polymer</i> , Vol. 36, No. 5, 975-980 (1995)
*	BL	Martini et al., "The Bioadhesive Properties of a Triblock Copolymer of $\epsilon$ -Caprolactone and Ethylene Oxide," <i>Intl. J. of Pharmaceutics</i> , Vol. 113, 223-229 (1995)
*	BM	Martini, L. et al., "Micellisation and Gelation of Triblock Copolymer of Ethylene Oxide and $\epsilon$ -Caprolactone, $CL_nE_mCL_n$ , in Aqueous Solution," <i>J. Chem. Soc. Faraday Trans.</i> 90(13): 1961-1966, 1994.

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 920041.416C1		APPLICATION NO. 10/721,835	
<b>INFORMATION DISCLOSURE STATEMENT</b> (Use several sheets if necessary)				APPLICANTS John K. Jackson et al.			
				FILING DATE November 25, 2003		GROUP ART UNIT	
<b>U.S. PATENT DOCUMENTS</b>							
*EXAMINER INITIAL	CA	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION YES NO	
	CB						
<b>OTHER PRIOR ART</b> (Including Author, Title, Date, Pertinent Pages, Etc.)							
*	CC	Nojima et al., "Crystallization of Block Copolymers II. Morphological Study of Poly(ethylene glycol)-Poly(ε-caprolactone) Block Copolymers," <i>Polymer J.</i> , Vol.24, No.11, 1271-1280 (1992)					
*	CD	Pechar et al., "Biodegradable Drug Carriers Based on Poly(ethylene glycol) Block Copolymers," <i>Macromol. Chem. Phys</i> 198:1009-1020 (1997)					
*	CE	Peracchia et al., "PEG-coated nanospheres from amphiphilic diblock and multiblock copolymers: Investigation of their drug encapsulation and release characteristics," <i>Journal of Controlled Release</i> 46: 223-231, 1997.					
*	CF	Peracchia et al., "PEG-Coated Nanospheres from Amphiphilic Diblock and Multiblock Copolymers: Investigation of Their Drug Encapsulation and Release Characteristics" <i>J. Controlled Release</i> 46: 223-231, 1997.					
*	CG	Ramaswamy, M. et al., "Human Plasma Distribution of Free Paclitaxel and Paclitaxel Associated with Diblock Copolymers," <i>Journal of Pharmaceutical Sciences</i> 86(4): 460-464, April 1997.					
*	CH	Shah et al., "Poly-DL-lactic acid: Polyethylene glycol block copolymers. The influence of polyethylene glycol on the degradation of poly-DL-lactic acid," <i>Journal of Biomaterials Science, Polymer Edition</i> 5(5): 421-431, 1994.					
*	CI	Wang and Qui., "Polycaprolactone-Poly(ethylene glycol) Block Copolymer, I: Synthesis and Degradability <i>In Vitro</i> ," <i>Polymers for Adv. Tech.</i> , Vol.4 ,363-366 (1992)					
*	CJ	Winternitz, C.I. et al., "Development of a Polymeric Surgical Paste Formulation for Taxol," <i>Pharmaceutical Research</i> 13(3): 368-375, 1996.					
*	CK	Youxin et al., "In-Vitro Degradation and Bovine Serum Albumin Release of the ABA Triblock Copolymers Consisting of Poly(L+)Lactic Acid), or Poly(L+)Lactic Acid-Co-Glycolic Acid) A-blocks Attached to Central Polyoxyethylene B-blocks," <i>J. of Controlled Release</i> 32:121-128 (1994)					
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant(s).							

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**U.S. PATENT DOCUMENTS**

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	DA						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	DB					

**OTHER PRIOR ART** (Including Author, Title, Date, Pertinent Pages, Etc.)

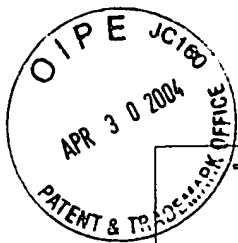
*	DC		Zhang et al., "Development of Biodegradable Polymeric Paste Formulations for Taxol: An <i>In Vitro</i> and <i>In Vivo</i> Study," <i>Intl. J. of Pharm.</i> , Vol. 137, 199-208 (1996)
*	DD		Zhang, X. et al., "Anti-tumor efficacy and biodistribution intravenous polymeric micellar paclitaxel," <i>Anti-Cancer Drugs</i> 8: 696-701, 1997.
*	DE		Zhu et al., "'Super Microcapsules' (SMC). I. Preparation and Characterization of Star Polyethylene Oxide (PEO)-Polylactide (PLA) Copolymers," <i>Journal of Polymer Science: Part A: Polymer Chemistry</i> , Vol. 27, 2151-2159 (1989)
*	DF		Zhu et al., "Preparation, Characterization, and Properties of Polylactide (PLA)-Poly(ethylene Glycol) (PEG) Copolymers: A Potential Drug Carrier," <i>Journal of Applied Polymer Science</i> 39: 1-9, 1990.
	DG		
	DH		
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	DK		
	DL		

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# TRANSMITTAL FORM

(To be used for all correspondence  
after initial filing)

Application Number	10/721,835
Filing Date	November 25, 2003
First Named Inventor	John K. Jackson
Art Unit	
Examiner Name	
Attorney Docket No.	920041.416C1

## ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> CD(s), Number of CD(s) _____
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Request for Corrected Filing Receipt	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Amendment/Response	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Declaration	<input checked="" type="checkbox"/> Return Receipt Postcard
<input checked="" type="checkbox"/> Information Disclosure Statement; Form PTO-1449	<input type="checkbox"/> Statement under 37 CFR 3.73(b)	<input type="checkbox"/> Additional Enclosure(s) (please identify below):
<input type="checkbox"/> Cited References	<input type="checkbox"/> Terminal Disclaimer	_____
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Request for Refund	_____
<input type="checkbox"/> Response to Missing Parts under 37 C.F.R. 1.52 or 1.53		_____
<input type="checkbox"/> Response to Missing Parts/Incomplete Application		_____

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Individual Name	Jeffrey C. Pepe, Ph.D. Reg. No. 46,985	Customer Number <b>00500</b>
Signature		
Date	April 27, 2004	

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Lawrence Teague	
Signature		Date: April 27, 2004

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. 476825